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Subject: Inside EPA- Under Industry Pressure, EPA Plans Revisions For Acrylonitrile Risk Study

I think there's a decent chance we could get some Hill inquiries on this.

Under Industry Pressure, EPA Plans Revisions For Acrylonitrile Risk Study

Posted: May 24, 2012

EPA is delaying and revising its pending risk assessment of the common plastics ingredient acrylonitrile (AN) in an effort to address what it says are scientific issues with the draft released last summer, a move long sought by industry, which has raised qualms with the agency's choice of studies that serve as the basis of the assessment.

EPA now plans "to make further revisions to the acrylonitrile assessment to more fully address scientific issues in the assessment," according to an announcement the agency posted on its website. "The revised draft acrylonitrile assessment will be released for public comment and rigorous, independent expert peer review."

The new draft Integrated Risk Information System (IRIS) assessment, when released, will undergo peer review by the agency's new Chemical Assessment Advisory Committee of the Science Advisory Board (SAB). The new committee was created in response to growing concerns about the IRIS process by industry, lawmakers and the National Academy of Sciences (NAS).

EPA released an existing draft assessment late last June after stalling the document for a year pending further review of controversial studies from the Ramazzini Institute, an Italian laboratory whose studies industry argues overestimate cancer risks. While the agency sought public comment on that draft, it did not undergo peer review before EPA decided to delay and revise the assessment.

The June 2011 document released by the agency dropped its previous reliance on the Ramazzini data, a move that resulted in the agency scrapping an additional safety factor -- known as the age dependent adjustment factor (ADAF) -- it had originally proposed to add to further protect children.

EPA nevertheless proposed to tighten its 20-year-old cancer and non-cancer risk estimates, and suggested a

first-time reference dose (RfD), or the greatest amount of the substance the agency believes can be ingested daily over a lifetime without adverse effects.

The draft risk assessment called for an oral cancer slope factor of 5 per milligram per kilogram per day $(\text{mg/kg-day})^{-1}$, which tightens its 1991 estimate of oral cancer risk of $5.4 \times 10^{-1} (\text{mg/kg-day})^{-1}$, and a new cancer inhalation unit risk of 2×10^{-2} per milligram per cubic meter, which is also stronger than the 1991 estimate of 6.8×10^{-5} per microgram per cubic meter.

When finalized, the assessment could be used by the agency to drive a host of new air toxics, water and cleanup standards for the chemical, which is present at several waste sites, including some on the agency's Superfund list.

Industry has long found fault with the draft, and AN has been pointed to by top Senate Republicans as an assessment that should be delayed pending the full implementation of NAS' recommended changes to IRIS.

Assessment 'Deficiencies'

The industry's AN Group, which represents manufacturers, in a March letter to EPA called on the agency to make further revisions to the assessment, arguing that "because of serious substantive and procedural deficiencies, the current draft assessment violates the principles of sound science, scientific integrity and transparency that the Obama Administration has directed all agencies to follow, as well as the Agency's own guidance and policies on data quality."

In particular, wrote Robert Fensterheim, executive director of the group, in the March 8 letter, EPA needs to make public the Blair et al. study and data used in the draft to form the basis of the inhalation unit risk value; look to other peer reviewed assessments of AN and reconcile or justify the difference in conclusions between the EPA draft and those other documents; and make those changes prior to sending the document for peer review, arguing that failing to do so would violate a number of EPA guidance and policies.

"EPA should ensure that the planned peer review is rigorous and that peer reviewers and stakeholder are provided with comprehensive background information, including access to key studies, data and models," Fensterheim wrote.

Until the data quality and other issues are resolved, Fensterheim continued, "at most, the [peer review] panel would only be able to conclude that the record is incomplete."

Further, the letter continues, given the effect the assessment could have on the market for and use of AN, it should have to meet the Office of Management and Budget's standards of review for a Highly Influential Scientific Assessment. "As such, the agency's peer review should be rigorous and provide reviewers with sufficient background information, including access to key studies, data and models, to perform their role as peer reviewers," Fensterheim wrote.

EPA on its website says that under the new schedule, the assessment will be revised and prepared for peer review by the second quarter of fiscal year 2013. While the agency in September said the assessment would be completed in FY12, its IRISTrack website now says the final document is slated for release in the first quarter of FY14. -- *Jenny Hopkinson* (jhopkinson@iwpnews.com This e-mail address is being protected from spambots. You need JavaScript enabled to view it)

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